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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/505,304 | 07/11/2005 | Ian Revie | 1781-0010 | 6005 |

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MAGINOT, MOORE & BECK, LLP
CHASE TOWER
111 MONUMENT CIRCLE
SUITE 3250
INDIANAPOLIS, IN 46204

EXAMINER

KASZTEJNA, MATTHEW JOHN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3739

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|----------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/505,304 | Applicant(s) REVIE ET AL. | |
| | Examiner Matthew J. Kasztejna | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 12-16 and 19-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 12-16 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on September 25, 2006, amended 5-8 and 15-16 and new claims 19-24 and canceled claims 9-11 and 17-18 are acknowledged. The current rejections of the claims are *withdrawn*. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-3, 5, 8, 12-13, and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Kienzle, III et al. (U.S. Patent No. 6,478,802).

In regard to claims 2-3, 5, 8, 12-13, and 19-21, Kienzle, III et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the shaft bearing a plurality of markers rings arranged in a predetermined pattern, which are more reflective than the surface of the shaft (see Figs. 1-2 and Col. 4, Lines 25-43), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information

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relating to the position and orientation of the reel drill bit relative to the receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6, 14-15 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Gillies et al. (U.S. Patent No. 6,272,370).

In regard to claims 4, 6, 14-15 and 22-23, Kienzle, III et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the shaft bearing a plurality of markers rings arranged in a predetermined pattern (see Figs. 1-2 and Col. 4, Lines 25-30), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. are silent with respect wherein the planes defined by the axially spaced edges of each ring are parallel to one another and perpendicular to the drill bit axis. However, Kienzle, III et al.

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teach that any arrangement of emitters that allows the localizer to determine the pose of the drill emitter coordinate frame with sufficient accuracy may be used without departing from the instant invention. Furthermore, Gillies et al. teach of an analogous medical instrument 1 comprised of an elongate shaft with a plurality of MR-visible markers 6 disposed at the distal end to provide easily identifiable reference points for trackability and localization under MR imaging and X-ray fluoroscopy (see Figure 1 and col. 25, lines 39-43). Figure 1 shows that the planes defined by the axially spaced edges of each marker 6 are parallel to one another and perpendicular to the axis of the shaft 2. It would have been obvious to one skilled in the art at the time the invention was made to arrange the marker rings around the shaft of the instrument of Kienzle, III et al. in order to allow for more efficient and reliable tracking and positioning of the instrument during surgery as taught by Gillies et al.

Claims 7, 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Ben-Haim (U.S. Patent No. 6,203,493).

In regard to claims 7, 16 and 24, Kienzle, III et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the shaft bearing a plurality of markers rings arranged in a predetermined pattern (see Figs. 1-2 and Col. 4, Lines 25-30), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the

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receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. are silent with respect wherein the rings are marked on a sleeve which is fitted onto the instrument. Ben-Haim teaches a similar tracking device for an endoscope comprised of a sheath 20 having a plurality of sensors 22 spaced along the axis of the endoscope (see Figure 1). It would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the instrument of Kienzle, III et al. with a sheath containing the markers 6, in the manner disclosed by Ben-Haim, as Ben-Haim demonstrates that sheaths containing radio-opaque markers for placement over an surgical device are well known in the art.

Response to Arguments

Applicant's arguments with respect to claims 2-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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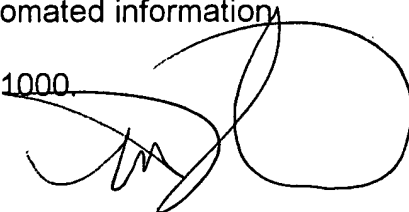
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK *MJK*
12/5/06



LINDA C. M. DVORAK
SUPERVISOR
EXAMINER